



**NOV 19 2001**

## **WARNING LETTER**

Mr. Prakit Likitlersuang  
Deputy Managing Director  
May Ao Foods Company  
568 Moo 2, Bangpoo Industrial Estate, Sukhumvit Rd.  
Bangpoomai, Muang, Samutprakarn  
Thailand

Dear Mr. Likitlersuang:

We inspected your firm located at 568 Moo 2, Bangpoo Industrial Estate, Sukhumvit Rd., on March 15, 2000, and found that you have serious deviations from the U.S. Seafood HACCP regulations (21 CFR, Part 123). These deviations cause your frozen raw black tiger shrimp to be in violation of Section 402(a)(4) of the U.S. Federal Food, Drug, and Cosmetic Act. You can find this Act and the Seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations were as follows:

You must have a HACCP plan that lists the critical limits that must be met to comply with 21 CFR, Part 123.6(c)(3).

- Your firm's HACCP plan for **Frozen Raw Black Tiger Shrimp** lists a critical limit (i.e., 100 ppm) for sulfites at the Receiving critical control point. Setting a "limit" for sulfites is not an appropriate control because it does not address the hazard of undeclared sulfites. Since your firm does not intend to declare sulfites on the labels of shrimp destined for the United States, you must implement a control strategy that ensures that there is no detectable level of sulfites in any lots of incoming raw material at Receiving. The *Fish & Fisheries Products Hazards & Controls Guidance*: Third Edition, Chapter 19, provides guidance on how to address this hazard of undeclared sulfites.

The HACCP program summary states that shrimp for the Asian and European markets are treated with sulfites during processing. These shrimp are then washed and soaked

several times to remove the sulfites. We do not believe that this wash/soak process would guarantee removal of the sulfite residues to an undetectable level. If your contention is that all of your shrimp are considered sulfite-free because of this wash/soak process, you must provide additional supporting data and information to support this claim.

If your firm is unable to adopt and implement a control strategy that ensures that all shrimp shipped from your facility to the United States are free from detectable levels of sulfites, we recommend that you adopt a strategy that involves a sulfite declaration on the labels of your product.

- You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR, Part 123.11(b). However, your firm did not adequately monitor for exclusion of pests. The copy of the Sanitation Standard Operating Procedures provided both during the inspection and as part of the response packet does not adequately address the issue of monitoring for exclusion of pests. Your firm should provide copies of completed daily sanitation monitoring records, as well as copies of the exterminator's reports and/or contracts to support that a sanitation program for exclusion of pests has been effectively implemented.

Please respond in writing within six (6) weeks of receipt of this letter. Your response should specify things you are doing to correct these deviations. You may wish to include in your response documentation such a revised HACCP plan, HACCP summary, sanitation monitoring records, exterminator's reports or contract, or other useful information that would assist us in evaluating your corrections. If you believe the hazards listed above are not reasonably likely to occur in your products, you must provide the FDA with adequate, written documentation that clearly supports your reasoning.

If you cannot complete all corrections within six (6) weeks, we expect that you will respond in writing and explain the reason for your delay and state when you will correct any remaining deviations. Failure to provide us evidence of corrections to the deviations may result in your products being placed on "Detention Without Physical Examination."

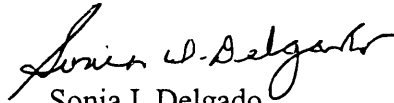
This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations (21 CFR, Part 123), and the Good Manufacturing Practice regulations (21 CFR, Part 110). You also have a responsibility to use procedures to prevent further violations of the U.S. Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the:

Food and Drug Administration  
Attention: Frank Sikorsky, Consumer Safety Officer  
Division of Enforcement and Programs  
Import Branch, HFS-606  
200 C Street S. W.,  
Washington, DC 20204

If you have questions regarding any issue in this letter, please contact Mr. Sikorsky at (202) 205-1922.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Sonia I. Delgado". The signature is fluid and cursive, with a large initial 'S'.

Sonia I. Delgado  
Deputy Director  
Division of Enforcement and Programs  
Office of Field Programs  
Center for Food Safety  
and Applied Nutrition